IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FILED
AUG 22 2019
U.S. DISTRICT COURT-WVND
WHEELING, WV 26003

NOVO NORDISK INC. and NOVO NORDISK A/S,

Plaintiffs,

v.

MYLAN INSTITUTIONAL LLC,

Defendant.

C.A. No. 1:19 CV 164
Kleeh

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Mylan Institutional LLC ("Mylan"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Mylan seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), 9,265,893 (the "'893 patent"), and RE41,956 (the "RE '956 patent"), which cover inter alia, Victoza® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under

the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

3. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Mylan Institutional LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 4901 Hiawatha Drive, Rockford, Illinois 61103. On information and belief, Mylan Institutional LLC is in the business of making and selling generic pharmaceutical products, which it distributes in the State of West Virginia and throughout the United States.

THE PATENTS-IN-SUIT

5. On July 31, 2001, the United States Patent and Trademark Office issued the '343 patent, entitled "Derivatives of GLP-1 Analogs," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '343 patent.

6. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '994 patent.

7. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '833 patent.

8. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '869 patent.

9. On September 30, 2014, the United States Patent and Trademark Office issued the '618 patent, entitled "Stable Formulation of Modified GLP-1," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '618 patent.

10. On February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled "Injection Button," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '893 patent.

11. On November 23, 2010, the United States Patent and Trademark Office issued the RE '956 patent, entitled "Dose Setting Limiter," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the RE '956 patent.

VICTOZA®

12. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '994, '833, '869, '618, '893, and RE '956 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

MYLAN'S ANDA

14. On information and belief, Mylan submitted ANDA No. 213155 ("Mylan's

ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Mylan's Product").

15. On information and belief, Mylan's ANDA refers to and relies upon the Victoza® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of Mylan's Product and Victoza®.

16. By letter to NNI and NNAS, dated July 8, 2019 for next day delivery on July 9, 2019 (the "Notice Letter"), Mylan stated that Mylan's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '994, '833, '869, '618, '893, and RE '956 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Mylan's Product (the "Paragraph IV Certifications"). Mylan attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certifications. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. Mylan's Notice Letter states that Mylan consents to personal jurisdiction and venue in the Northern District of West Virginia for purposes of any litigation arising related to Mylan's ANDA.

19. This Court has personal jurisdiction over Mylan by virtue of, inter alia, it having developed, manufactured, imported, marketed, offered to sell and/or sold generic drugs throughout the United States, including in the State of West Virginia and therefore having conducted business in West Virginia; having derived revenue from conducting business in West Virginia; and having engaged in systematic and continuous contacts with the State of West

Virginia.

20. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product, directly or indirectly, throughout the United States and in this District. Mylan's filing of Mylan's ANDA confirms this intention and subjects Mylan to the specific personal jurisdiction of this Court. *See Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

22. Venue is proper as to Mylan because Mylan has committed or aided, abetted, contributed to, and/or participated in patent infringement; intends a future course of conduct that includes acts of patent infringement in the State of West Virginia; and on information and belief, has a regular and established place of business in the State of West Virginia, inter alia, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in West Virginia. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of generic versions of Victoza®, directly or indirectly, throughout the United States and in this District.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,268,343

23. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-22 of this Complaint.

24. Mylan has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '343 patent.

25. Claims 1-3 and 14 of the '343 patent encompass liraglutide; claims 28, 29, 31, 32 and 33 of the '343 patent encompass pharmaceutical compositions comprising liraglutide; and claim 39 of the '343 patent encompasses a method of treating diabetes comprising administering to a patient a therapeutically effective amount of liraglutide. In the Notice Letter, Mylan has not contested its infringement of claims 1-2, 14 or 28-40 of the '343 patent. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '343 patent would infringe at least claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claim 39 of the '343 patent.

27. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '343 patent.

28. Novo Nordisk has no adequate remedy at law.

29. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,762,994

30. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-29 of this Complaint.

31. Mylan has infringed the '994 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by

submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '994 patent.

32. Claims 1-8 of the '994 patent encompass a mounting system for mounting two different needle arrangements. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '994 patent would infringe claims 1-8 of the '994 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '994 patent.

34. Novo Nordisk has no adequate remedy at law.

35. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

36. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-35 of this Complaint.

37. Mylan has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '833 patent.

38. Claims 1-15 of the '833 patent are directed to formulations comprising a GLP-1 agonist, a disodium phosphate dihydrate buffer, and propylene glycol. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing

clogging by replacing the isotonicity agent in a formulation with propylene glycol. In the Notice Letter, Mylan has not contested infringement of any claims of the '833 patent. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

39. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '833 patent.

40. Novo Nordisk has no adequate remedy at law.

41. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,579,869

42. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-41 of this Complaint.

43. Mylan has infringed the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '869 patent.

44. Claims 1-6 of the '869 patent are directed to a needle mount. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '869 patent would infringe claims 1-6 of the '869 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '869 patent.

46. Novo Nordisk has no adequate remedy at law.

47. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,846,618

48. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-47 of this Complaint.

49. Mylan has infringed the '618 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '618 patent.

50. Claims 1-3 and 5-14 of the '618 patent are directed to pharmaceutical formulations comprising liraglutide and certain excipients wherein the pharmaceutical formulation has a pH from 7.5 to 9.4. In the Notice Letter, Mylan has not contested infringement of any claims of the '618 patent. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '618 patent would infringe claims 1-3 and 5-14 of the '618 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

51. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '618 patent.

52. Novo Nordisk has no adequate remedy at law.

53. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,265,893

54. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-53 of this Complaint.

55. Mylan has infringed the '893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '893 patent.

56. Claims 1-6 of the '893 patent are directed to a push button connection for an injection device. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '893 patent would infringe claims 1-6 of the '893 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '893 patent.

58. Novo Nordisk has no adequate remedy at law.

59. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. RE 41,956

60. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-59 of this Complaint.

61. Mylan has infringed the RE '956 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of

the RE '956 patent.

62. Claims 1 and 2 of the RE '956 patent are directed to a dose limiting mechanism. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the RE '956 patent would infringe claims 1 and 2 of the RE '956 patent under 35 U.S.C. §§ 271(a), (b), and/or (c)..

63. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the RE '956 patent.

64. Novo Nordisk has no adequate remedy at law.

65. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Mylan and respectfully requests the following relief:

A. A judgment that Mylan has infringed the '343 patent;

B. A judgment that Mylan has infringed the '994 patent;

C. A judgment that Mylan has infringed the '833 patent;

D. A judgment that Mylan has infringed the '869 patent;

E. A judgment that Mylan has infringed the '618 patent;

F. A judgment that Mylan has infringed the '893 patent;

G. A judgment that Mylan has infringed the RE '956 patent;

H. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Mylan, its officers, agents, servants, and employees, and those persons in active

concert or participation with any of them, from manufacturing, using, offering to sell, or selling Mylan's Product within the United States, or importing Mylan's Product into the United States, prior to the expiration of the '343, '994, '833, '869, '618, '893, and RE '956 patents, including any extensions, adjustments, and exclusivities;

I. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '343, '994, '833, '869, '618, '893, and RE '956 patents, including any extensions, adjustments, and exclusivities;

J. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan's Product within the United States, or imports Mylan's Product into the United States, prior to the expiration of the '343, '994, '833, '869, '618, '893, and RE '956 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

K. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

L. Costs and expenses in this action; and

M. Such other relief as the Court deems just and proper.

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